

### **REMARKS**

Claims 1-3, 12, 13, 16-21, 34-35 and 41-43 are pending. Applicant notes that all amendments and cancellations of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), and without waiving the right to prosecute the amended or cancelled Claims (or similar Claims) in the future. Support for the growth factor limitations may be found in the specification, for example at page 23, lines 25-31, and in the Examples (e.g., Examples 8 and 9). Support for the remaining amendments may be found in the claims as originally filed.

Applicants thank Examiner Ton and SPE Paras for the telephonic interview on May 4, 2009 with the applicant's undersigned representative. In particular, the Applicants discussed removing the stem cell limitations from the claims. The Examiners recommended adding additional limitations on the processes and providing evidence that the cell populations are different from the starting UCM cell population. Applicants have attempted to do this in the claims as amended and redirect the Examiner's attention to the Mitchell Declaration, which documents differences between the claimed cell population produced by the claimed methods and unprocessed UCM cells as well as the cells population obtained by Purchio et al.

1. Claims 1, 3, 12, 13, 16-21, 34-35, and 41-43 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement;

2. Claims 1, 3, 12, 13, 16-21, 34-35, and 41-43 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement;

3. Claims 3, 34, and 35 stand rejected under 35 U.S.C. §102 as allegedly being anticipated by Purchio et al. (U.S. Pat. No. 5,919,702).

These rejections are addressed in order below.

**1. The claims are enabled.**

Claims 1, 3, 12, 13, 16-21, 34-35, and 41-43 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner states at page 4 of the Office Action that “the specification provides guidance with regard to isolation of a heterogenous population of cells, which includes UCMS cells.” The Examiner does on to state that “a heterogenous population of cells, which includes many different cells types, is used in Examples 8-9. It is unclear from the working examples if the effects that are reported (i.e., implantation of UCMS cells in Example 8, or transplantation of the population of cells into a Parkinsonian rat model) are produced by UCMS cells, or by other cells in the population.” Office Action, p. 5. The Examiner then argues that is would require undue experimentation in order to determine which cells would express the appropriate markers that would sufficiently arrive at obtaining a UCMS cell. *Id.*

The claims have been amended to refer to populations of cells that are produced from umbilical cord matrix (UCM). Applicants respectfully submit that this amendment moots the Examiner’s arguments supporting the enablement rejection. Since the claims are now directed to the population of cells produced by methods described in the specification, the issue of identifying particular UCMS cells, which the Examiner has focused the rejection on, is removed.

Applicants respectfully note that the currently pending claims are either method claims or product-by-process claims. Permitting an applicant to claim the inventions as product-by-process is based upon the principle that “when a man has made an invention, his right to a patent for it, or his right to a claim properly defining it, is not to be determined by the limitations of the English language.” *In re Bridgeford*, 357 F.2d 679, 682 (CCPA 1966). The Federal Circuit and its predecessors have invoked this principle to allow alternative forms of patent claims when the inventor needs the alternative language to adequately describe the invention. In particular, product-by-process claims are designed to enable the patentee “to claim an otherwise patentable product that resists definition by other than the process by which it is made.” *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985).

Unlike a regular product claim that limits the product by its structure, a “product-by-process” claim describes a product by the process used to make the structure, and recites this

process in the claim. M.P.E.P. § 2173.05(p) (*citing inter alia In re Moeller*, 117 F.2d 565 (CCPA 1941)). *See also* 3 Chisum on Patents § 8.05 (2002) (“A ‘product-by-process’ claim is one in which the product is defined at least in part in terms of the method or process by which it is made.”).

With this in mind, the enablement of the amended process and product-by-process claims must be reevaluated by the Examiner to determine if the specification provides enablement for the processes. In this regard, the Examiner has already indicated that the specification provides guidance with regard to isolation of a heterogenous population of cells, which includes UCMS cells, and that the cells are used in the working examples.

In the interview, the Examiners indicated that evidence demonstrating that population of cells that results from the process is different from the starting UCM cells would be useful in addressing the rejection. Such evidence is contained in the Mitchell Declaration submitted with the previous response. From the Declaration:

- The cell population produced by this process is obtained from all portions of the umbilical cord matrix and is enriched for cells that are negative for CD45. The population of cells in unprocessed Wharton’s Jelly contains a high percentage of cells that are positive for CD45. Mitchell Decl. ¶4.
- Table 1 of the Declaration provides an analysis of cell surface marker expression at the beginning of the passage process (P0) and Table provides an analysis of cell surface markers after passage 4 (P4). Mitchell Decl. ¶6.
- This data demonstrates the cell population obtained by the claimed methods is substantially different from the cell population in unprocessed Wharton’s jelly. Mitchell Decl. ¶7.

Application of the *Wands* factors to the claims as amended compels the conclusion that the claims are enabled. Nature of the invention: the invention is to a process for obtaining a population of cells from UCM. Breadth of the claims: the claims are directed to a process of obtaining a population of cells from UCM using a defined set of steps and the resulting population of cells. Guidance of the specification: the specification describes the starting

material (UCM), methods and media for processing the starting materials, and culture methods and media for selecting the claimed populations. Working examples: the specification provides working examples on how to process UCM cells and how to use the resulting cell populations (see, e.g., examples 8 and 9). State of the art: A person of ordinary skill in the art could easily replicate the processing steps, culture methods, and media described in the specification.

Predictability of the art and amount of experimentation necessary: While biotechnology is a generally unpredictable field, the culture methods and media taught in the specification are replicable by a person of ordinary skill in the art so that a predictable result can be obtained. These facts are confirmed in the Mitchell Declaration as described above and in paragraphs 12 and 13 of the Mitchell Declaration.

For the forgoing reasons, Applicants request that the enablement rejection be withdrawn.

**2. The claims have an adequate written description.**

Claims 1, 3, 12, 13, 16-21, 34-35, and 41-43 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. On page 6 of the Office Action, the Examiner states that the Applicants previous arguments were unpersuasive because “the amended claims are directed to a population of cells that comprise UCMS cells. However, the claims require UCMS cells.” The Examiner goes on to argue that “there is no guidance in the working examples with regard to the particular, identifying characteristics of a UCMS cell, only to a population of cells which comprise UCMS cells (*i.e.*, a heterogenous population of cells).” The claims have been amended to delete the reference to stem cells. Accordingly, the basis for the Examiner’s rejection appears moot, as the population of cells is now claimed. As indicated by the Examiner, the specification provides guidance for such a population of cells. Office Action p. 4.

Applicants further note that the MPEP specifically approves product-by-process claims: “A product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper. *In re Luck*, 476 F.2d 650, 177 USPQ 523 (CCPA 1973); *In re Pilkington*, 411 F.2d 1345, 162 USPQ 145 (CCPA 1969); *In re Stepan*, 394 F.2d 1013, 156 USPQ 143 (CCPA 1967).” MPEP 2173.05(p). To satisfy the written description

requirement of a “product-by-process” claim, the inventors need only describe the process used to create the cell population, not structural or other features of the cells. *See In re Edwards*, 568 F.2d 1349, 1352 (CCPA 1978).

Accordingly, Applicants request that the written description rejection be withdrawn.

**3. The claims are not anticipated.**

Claims 3, 34, and 35 stand rejected under 35 U.S.C. §102 as allegedly being anticipated by Purchio et al. (U.S. Pat. No. 5,919,702). In response to the Applicant’s arguments, the Examiner states that “given that Purchio teaches cells that are isolated from the same source, and produced by methods that are taught in the specification, the Wharton’s jelly culture that is taught by Purchio anticipates the instant claims.” Applicants have amended the claims to specify that the cells are cultured in the presence of EGF and PDGF. Purchio does not teach use of these growth factors in the culture media. Therefore, the claimed process is novel over Purchio and the cell population produced by the claimed process is different than the cell population produced by Purchio as established in the Mitchell Declaration.

The rejected claims are product-by-process claims. These product-by-process claims are not anticipated if the resulting product, in this case a cell population, is different than the cell population obtained by Purchio. The Mitchell Declaration conclusively establishes that the population obtained is different. Mitchell Declaration ¶¶ 4-11 and in particular ¶ 8. As detailed in the Mitchell Declaration, the cell population obtained by the claimed process steps is different from the Purchio method prechondrocytes isolated from Wharton’s jelly cells in terms of cell surface markers, morphology, and differentiation potential. Accordingly, Applicants request that the anticipation rejection be withdrawn.

**CONCLUSION**

Applicants believe that the claims are in condition for allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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